DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 526

ADM

Intramammary Dosage Forms; Ceftiofur

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Pharmacia & Upjohn Co., a Division of Pfizer, Inc. The NADA provides for the veterinary prescription use of ceftiofur hydrochloride suspension, by intramammary infusion, for the treatment of clinical mastitis in lactating dairy cattle.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.gov.*

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–238 for SPECTRAMAST LC (ceftiofur hydrochloride) Sterile Suspension. The NADA provides for the veterinary prescription use of ceftiofur hydrochloride suspension, by intramammary infusion, for the treatment of clinical mastitis in lactating dairy cattle associated with coagulase-negative staphylococci, *Streptococcus dysgalactiae*, and *Escherichia coli*. The application is approved as of February 9, 2005, and the regulations are amended in 21 CFR part 526

by adding new § 526.314 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(d)(5) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning February 9, 2005.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 526

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 526 is amended as follows:

PART 526—INTRAMAMMARY DOSAGE FORMS

■ 1. The authority citation for 21 CFR part 526 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 526.314 is added to read as follows:

§ 526.314 Ceftiofur.

(a) *Specifications*—(1) Each 10-milliliter (mL) syringe contains ceftiofur hydrochloride suspension equivalent to 125 milligrams (mg) ceftiofur.

(2) [Reserved]

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.113 of this chapter.

(d) *Conditions of use in cattle*—(1) *Lactating cows*—(i) *Amount.* 125 mg per affected quarter using product described in paragraph (a)(1) of this section. Repeat treatment in 24 hours. Once daily treatment may be repeated for up to 8 consecutive days.

(ii) *Indications for use.* For the treatment of clinical mastitis in lactating dairy cattle associated with coagulase-negative staphylococci, *Streptococcus dysgalactiae*, and *Escherichia coli*.

(iii) *Limitations.* Milk taken from cows during treatment (a maximum of eight daily infusions) and for 72 hours after the last treatment must not be used for human consumption. Following label use for up to 8 consecutive

days, no preslaughter withdrawal period is required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: 2/17/05
February 17, 2005.

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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